Standard Process®

December 15, 1999

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The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

(1) Promotes healthy immune system function.

(2) Vitamin A helps the body maintain healthy mucous membranes, urinary tract and lungs. Both vitamin B6 and iron support immune response and help support healthy blood. Zinc also enhances immune function.

(3) Keeps your circulatory system healthy.

(4) Niacin helps promote healthy cholesterol levels in the blood. Vitamin B6 discourages the formation of homocysteine, helping the body to keep this substance within an acceptable range.

(5) Maintains cellular health.

(6) Niacin functions as two important co-enzymes that are key to cell respiration, carbohydrate and protein metabolism, and lipid synthesis. Vitamin B6 plays a direct role in regulating proper cell growth and division. It also promotes red blood cell formation. Vitamin B6 helps maintain the sodium/potassium balance, so important in helping prevent some sources of water retention in the body. Vitamin A helps maintain and repair epithelial cells to promote healthy skin and mucous membranes. Iron and copper join forces to produce hemoglobin to oxygenate red blood cells. Iodine helps metabolize excess fat, while zinc assists in protein synthesis and collagen formation.

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(7) Supports digestive function.

(8) Both niacin and vitamin B6 are needed to produce hydrochloric acid that is used to digest food properly. Niacin is involved with normal bile secretion and stomach fluids.

(9) Promotes normal growth and reproduction.

(10) Vitamins A, B6, and niacin, plus minerals iron, iodine, and zinc are intimately involved with different processes of growth and reproduction.

(11) Combines exclusive animal tissue extracts, such as the bovine liver fat extract Yakriton, with additional supportive nutritional concentrates from whole food sources to help support the complex and countless functions of the liver.

(12) Whole desiccated animal tissue proteins, Protomorphogen™ extracts and Cytosol™ extracts support the corresponding organs in humans.

These statements are made for a dietary supplement containing a proprietary blend of bovine liver PMG™ extract, spanish black radish (root), bovine liver, calcium lactate, beet (root), carrot (root), Tillandsia usneoides, dried beet (leaf) juice, betaine hydrochloride, magnesium citrate, choline bitartrate, soy (bean), oat flour, bovine kidney, bovine prostate, bovine adrenal Cytosol™ extract, defatted wheat (germ), bovine liver fat extract, bovine orchic extract, ascorbic acid, flaxseed oil extract, and mixed tocopherols. Other ingredients include gelatin, zinc liver chelate, iron liver chelate, water, potassium bicarbonate, calcium stearate, niacinamide, copper liver chelate, natural colors, pyridoxine hydrochloride, vitamin A palmitate, and prolamine iodine (zein). The name of the product is Livaplex®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann M. Holden

Ann Holden
Standard Process Inc.